

REMARKS

The Office Action mailed March 2, 2006, has been received and reviewed. Claims 1, 3, 10 through 20, 22, 28 through 45, 47, 48, 50 through 53, 55 through 61 and 64 are currently pending in the application. Claims 1, 3, 10 through 20, 22, 28 through 45, 47, 48, 50 through 53, 55 through 61 and 64 stand rejected. Applicants have amended claims 17, 35, 48, 55, 57, 58, 60 and 61, and respectfully request reconsideration of the application as amended herein.

**35 U.S.C. § 102(b) Anticipation Rejections**

Anticipation Rejection Based on U.S. Patent No. 5,024,842 to Edgren et al.

Claims 1, 11 through 14, 36 through 38, 40 through 45, 53, 56 and 64 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Edgren et al. (U.S. Patent No. 5,024,842). Applicants respectfully traverse this rejection, as hereinafter set forth.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Claims 1, 11 through 14, 36 through 38, 40 through 45, 53, 56 and 64 have been cancelled without prejudice to pursue the subject matter of the same in a related application. Therefore, the rejection is moot.

Anticipation Rejection Based on U.S. Patent No. 5,728,396 to Peery et al.

Claims 1, 3, 10 through 16, 34, 36 through 45, 47, 53, 56, 59 and 64 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Peery et al. (U.S. Patent No. 5,728,396). Applicants respectfully traverse this rejection, as hereinafter set forth.

Claims 1, 3, 10-16, 36-45, 40 through 45, 47, 53, 56, 59 and 64 have been cancelled without prejudice to pursue the subject matter of the same in a related application. Therefore, the rejection is moot.

### 35 U.S.C. § 103(a) Obviousness Rejections

Obviousness Rejection Based on U.S. Patent No. 5,024,842 to Edgren et al. in view of U.S. Patent No. 5,728,396 to Peery et al.

Claims 17 through 20, 22, 28 through 33, 35, 48, 50 through 52, 55, 57, 58, 60 and 61 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Edgren et al. (U.S. Patent No. 5,024,842) in view of Peery et al. (U.S. Patent No. 5,728,396). Applicants respectfully traverse this rejection, as hereinafter set forth.

M.P.E.P. 706.02(j) sets forth the standard for a Section 103(a) rejection:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, **the prior art reference (or references when combined) must teach or suggest all the claim limitations.** The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). (Emphasis added).

Edgren is relied upon as teaching a method of processing a rate controlling member in the form of a polymeric subcoat coating composition comprising polyalkylene oxides. The method further includes coating (i.e., spraying or dipping) the subcoat and an overcoat material onto a drug, and annealing the ingredients to form an annealed coat on the drug. (Edgren at Col. 7, line 68 to Col. 8, line 20). Edgren is drawn to methods of administering a drug to the gastrointestinal tract at a controlled rate. (Id. at Col. 13, line 49 to Col. 14, line 15). Peery is relied upon as teaching a semipermeable plug that may comprise a polyurethane or a polyether blocked polyamide copolymer.

Claims 17, 48, 57, and 58 are drawn to methods for processing rate controlling membranes that require, *inter alia*, providing a membrane formed from a material selected from the group consisting of polyurethanes and polyether blocked amides copolymers, and after heating and relaxation steps, incorporating the membrane into an implantable controlled drug

delivery device. As acknowledged by the Examiner, Edgren does not teach or suggest controlling membranes comprising polyurethane or a polyether blocked polyamide copolymer or incorporation of the membrane into an implantable controlled drug delivery device. In fact, Edgren teaches away from this concept, as it is expressly drawn to use of different materials adapted for use as coatings directly on drugs, and not for incorporation into an implantable device.

Claims 35, 55, 60, and 61 are drawn to rate controlling membranes that require, *inter alia*, providing a membrane formed from a material selected from the group consisting of polyurethanes and polyether blocked amides copolymers, and the membrane has decreased variability of water uptake from membrane to membrane. As acknowledged by the Examiner, Edgren does not teach or suggest either of these limitations. Peery does not overcome this problem, as it does not teach or suggest a membrane having decreased variability of water uptake and is not properly combinable with Edgren, as previously discussed.

Additionally, there is no general motivation or suggestion to combine Edgren with Peery for purposes of making any of the preceding claims obvious. As previously discussed, Edgren teaches application of coatings as a layer directly onto drugs, followed by annealing of the coating on the drug. In contrast, Peery teaches use of semipermeable plugs 24 and 26 that are inserted into a reservoir (through, e.g., injection molding) and act to swell upon exposure to fluid in a body cavity to form a tight seal with the reservoir. (Peery at Col. 5, lines 5-9). Thus, there is no motivation to combine the drug and annealed coating combination of Edgren, with a swellable, semipermeable plug in the implantable device of Peery.

The cited references also do not provide a motivation to combine because the combination of Edgren and Peery would render the drug of Edgren inoperable for its intended purpose. If a proposed modification would render the prior art invention being modified inoperable for its intended purpose, then there is no suggestion or motivation to make the proposed modification. M.P.E.P. § 2143.01. If the semipermeable plug of Peery was modified to be used as a coating in the drug of Edgren, the resulting combination would still be a coated, sustained release drug and not a device, and more importantly, would be inoperable because the

drug would likely not be release from a layer of semipermeable plug material that was designed to expand and stay solid in an aqueous environment.

The nonobviousness of independent claims 17, 35, 55, 48, 57, 58, 60 and 61 precludes a rejection of claims 18-20, 28-33, and 50-52 which depends therefrom because a dependent claim is obvious only if the independent claim from which it depends is obvious. *See In re Fine*, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988), *see also* MPEP § 2143.03. Therefore, the Applicants respectfully request that the Examiner withdraw the 35 U.S.C. § 103(a) obviousness rejection to claims 17-20, 22, 28-33, 35, 48, 50-52, 55, 57, 58, 60 and 61 .

#### **ENTRY OF AMENDMENTS**

The amendments to claims 17, 35, 55, 48, 57, 58, 60, and 61 above should be entered by the Examiner because the amendments are supported by the as-filed specification and drawings and do not add any new matter to the application. Further, the amendments do not raise new issues or require a further search.

#### **CONCLUSION**

Claims 17-20, 28-32, 34, 35, 48, 50-52, 55, 57, 58, 60 and 61 are believed to be in condition for allowance, and an early notice thereof is respectfully solicited. Should the

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Examiner determine that additional issues remain which might be resolved by a telephone conference, the Examiner is respectfully invited to contact Applicants' undersigned attorney.

Respectfully submitted,



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